Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee

October 26, 2005

Questions	to	the	Com	mittee

1.	Do the available data for the Emsam 20 mg patch support the reasonable safety of this formulation without the need for dietary restrictions? [Vote requested]
2.	If the Emsam 20 mg patch formulation could be considered reasonably safe for marketing without the need for dietary restrictions, would it be acceptable to market the 20 mg patch without dietary restrictions and at the same time require dietary

restrictions for the 30 and 40 mg patch strengths? [Vote requested]